Attorney Docket # 5434-8 Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
Jamie CRAWFORD et al.
Serial No.: 10/699,971
Filed: November 3, 2003
For: Safety Shield System For A Syringe

Examiner: Mark K. Han
Group Art: 3763

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RESPONSE TO REQUIREMENT FOR ELECTION OF SPECIES/RESTRICTION

SIR:

In response to the Requirement for Restriction Election of Species dated October 5, 2005, applicants submits as follows:

Applicant elects, with traverse, Species II (Figure 12) on which claims 1-13, 16-39 and 42-43 read. Please note that claims 1-13, 16-39 and 42-43 are generic to all of the "species" indicated in the October 5, 2005 Office Action.

In the Office Action, the Examiner states that "currently, no claim is generic". Applicant respectfully disagrees and contends that claims 1-13, 16-39 and 42-43 **are**

generic to all of the species. Examples of how some of these claims read on the species are provided below.

Independent claim 1 recites:

Claim 1 A medical device for delivering a medicament to a patient, comprising: (a) a syringe assembly comprising: (i) a barrel having a forward end and a rear end and defining a reservoir within which the medicament may be contained; (ii) a needle cannula having a forward tip and being coupled to said forward end of said barrel and in fluid communication with said reservoir; (iii) a plunger having a first end with a stopper positioned in said reservoir and a second end having a thumb pad for receiving medicament delivery pressure for causing said plunger to move within said reservoir to cause the medicament to be expelled from said reservoir; (b) a shield releasably mounted on a front portion of said barrel at a first position; and (c) an urging member for urging said shield in a forward direction relative to said syringe assembly, said shield being movable from said first position to a second position against the urgency of said urging member when said needle cannula is inserted into a patient for delivery of the medicament and said shield being moveable from said second position to a third position by the urgency of said urging member upon removal of said needle cannula from said patient, wherein said forward tip of said needle cannula is covered by said shield when said shield is in said third position.

All of the "Species" use a syringe assembly. Thus, elements (a)(1) - (a)(iii) of claim 1 read on all of the species. A shield (22) which is releasably mounted on a front portion of the syringe barrel is shown in Fig. 1. The specification explains that the shield moves within a tracks defined in a front portion (60) of the barrel. The tracks are depicted in all of the species (elements, 62, 64 in Fig. 1; elements 62', 64' in Fig. 12, lock-out tracks 62a, 62b in Fig. 13 (track 64 is not shown in Fig. 13), and tracks 362, 364 in Fig. 14). Thus, element (b) of claim 1 reads on all of the species. Lastly, element (c) of claim 1 recites that the shield moves from the first position, to a second position and then to a third position as the shield slides along the tracks (e.g., tracks 62, 64). This occurs in all of the species. Hence, claim 1 is generic to all of the species.

Claims 2-13 and 16-24 also read on all of the species. For example, all of the species include a "means for preventing ... after the shield is moved to the second position" as recited in claim 2. *See*, "one-way entry step" elements 68, 68', and 368 in

Figs. 1, 12 and 14, respectively. A one-way entry step is present but not shown in the embodiment of Fig. 13. Likewise, claim 3 reads on all of the species in that they all include an entry track (64, 64', 364), and a lock-out track (62, 62', 362) which are joined at an intersection, and wherein a pin 66 is guided along the tracks. Still other dependent claims from claim 1 are generic to all species.

Independent claim 25 is also generic to all species. This claim recites:

Claim 25 A combination comprising a medical syringe and a safety shield assembly, said medical syringe comprising a barrel having a forward end and a rear end and defining a reservoir within which the medicament may be contained, a needle cannula having a forward tip and being coupled to said forward end of said barrel and in fluid communication with said reservoir, and a plunger having a first end with a stopper positioned in said reservoir and a second end having a thumb pad for receiving medicament delivery pressure for causing said plunger to move within said reservoir to cause the medicament to be expelled from said reservoir; and said safety shield assembly comprising a shield releasably mounted on a front portion of said barrel at a first position, and an urging member for urging said shield in a forward direction relative to said barrel, said shield being movable from said first position to a second position against the urgency of said urging member when said needle cannula is inserted into a patient for delivery of the medicament and said shield being moveable from said second position to a third position by the urgency of said urging member upon removal of said needle cannula from said patient, wherein said forward tip of said needle cannula is covered by said shield when said shield is in said third position.

All of the species contain the elements of claim 25 and its dependent claims. For example, all of the species include a medical syringe and a safety shield assembly. The syringe includes a barrel, a needle cannula and a plunger for administering medicine contained in the syringe reservoir. A shield 22 is releasable mounted on the front of the barrel and is movable from a first position to a second position against urgency of an urging member 42, and then from the second position to a third position by force exerted on the shield from the urging member when the needle cannula is removed from a patient. All of the species depicted in Figs. 1, 12, 13, and 14 operate in this manner. Furthermore, each of the species includes an entry and a lock-out track, as

recited in dependent claim 26, which are joined at an intersection for accommodating a radial projection or pin 38, 338. The pin may be on either the barrel or shield, depending on whether the tracks are formed in the shield or barrel.

Independent claim 32 is also generic to all species. This claim recites:

Claim 32 A shield assembly for connection to a syringe barrel for preventing inadvertent needle sticks after use of the syringe, the shield system comprising (a) a cylindrical portion connectable to a front end of the syringe barrel, (b) a shield releasably mounted on said cylindrical portion at a first position, and (c) an urging member for urging said shield in a forward direction relative to the syringe barrel, said shield being movable from said first position to a second position against the urgency of said urging member when a needle cannula of the syringe is inserted into a patient for delivery of the medicament and said shield being moveable from said second position to a third position by the urgency of said urging member upon removal of the needle cannula from the patient to cover the tip of the needle cannula connected to the forward end of the syringe barrel.

Element (a) of claim 32 is shown as cylindrical barrel portion 60 in Fig. 1 and is also depicted in Figs. 12, 13 and 14. Likewise, the shield 22 is shown releasably mounted to the cylindrical portion 60, i.e. to move along the tracks 62, 64 (Fig. 1), the tracks 62', 64' (Fig. 12), the tracks 62a, 64a (Fig. 13) and the tracks 362, 364 (Fig. 14). All of the species include an "urging member" 42 for urging the shield in the forward direction relative to the syringe barrel. The shield in all of the species further moves from a first position, to a second position, and then to a third position.

Lastly, independent claim 43 is also believed to be generic to all of the species. This claim recites:

Claim 43 A medical device for delivering a medicament to a patient, comprising: (a) a syringe assembly comprising: (i) a barrel having a forward end and a rear end and defining a reservoir within which the medicament may be contained; (ii) a needle cannula having a forward tip and being coupled to said forward end of said barrel and in fluid communication with said reservoir; and (iii) a plunger having a first end with a stopper positioned in said reservoir and a second end having a thumb pad for receiving medicament delivery pressure for causing said plunger to move within said reservoir to cause the medicament to be expelled from said reservoir; (b) a shield releasably mounted on a front portion of said barrel at a first position; (c) means for urging said shield in a forward direction relative to said syringe assembly; (d) means for retaining said shield in said first position; (e) means for allowing

movement of said shield from said first position to a second position against the urgency of said urging member when said needle cannula is inserted into a patient for delivery of the medicament; and (f) means for allowing movement of said shield from said second position to a third position by the urgency of said means for urging upon removal of said needle cannula from said patient, wherein said forward tip of said needle cannula is covered by said shield when said shield is in said third position.

All of the species use a syringe assembly. Thus, elements (a)(1) - (a)(iii) of claim 43 read on all of the species. Furthermore, all of the species include a shield assembly 22 mounted to the front of the syringe barrel at a first position. An urging means such as element 42 is used in all of the species to urge the shield in a forward direction. Means for allowing movement of the shield from the first position to a second position is shown, for example, as the entry track 64, 64' and 364, and means for allowing movement of the shield from the second position to the third position is shown as lock-out tracks 62, 62' and 362.

There are two criteria for making a proper Restriction Requirement (see MPEP §803):

(A) The inventions must be independent or distinct as claimed; and

(B) There must be a serious burden on the Examiner to examine the inventions.

With regards to criteria (A), the general test as to when claims are restricted to different species is the fact that one claim recites limitations which under the disclosure are found in a first species but not in a second, while a second claim recites limitations disclosed only for a second species and not the first. In other words, for claims to be properly restricted to different species, the claims must recite the mutually exclusive characteristics of such species. *See*, MPEP § 806.04(f).

Here, as shown above, all of the claims with the exception of claims 14, 15, 40 and 41 read on **all** of the species. Thus, criteria (A) is not met.

Applicant also submits that criteria (B) has not been met because the Examiner has failed to make a *prima facie* showing of a serious burden. As stated in the MPEP, a serious burden may be *prima facie* shown by the Examiner "by appropriate explanation of separate classification, or separate status in the art, or a different field of search" (MPEP, §803). Because the Examiner has failed to show any of these, or even to make any statement concerning the serious burden criteria, the Examiner has not made a proper Restriction Requirement.

Furthermore, applicant asserts that examining all of the species shown by FIGS. 1, 12, 13, and 14 would not be a serious burden. It is believed that all of the species will fall within the same classification (e.g., class 604, subclass 192).

Although applicant has provisionally elected an alleged species as required by 35 U.S.C. §121, applicant respectfully traverses the requirement and requests reconsideration and withdrawal of the Election Requirement under 37 C.F.R. §1.143, in view of the arguments made above.

Applicants reserves the right to pursue the non-elected claims in a divisional application prior to issuance of a patent on the instant application.

Any additional fees or charges required at this time in connection with the application may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
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By _____

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